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U.S. DISTRICT COURT
N.D. OF ALABAMA

**IN THE UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ALABAMA**
**SOUTHERN DIVISION**

| | |
|---|---|
| **HYGIA HEALTH SERVICES, INC.**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**UNITED STATES FOOD & DRUG ADMINISTRATION**<br><br>**Defendant.** | **Case No._____** |

# COMPLAINT

## Nature of the Action

1. This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, for injunctive relief, attorney fees, and other appropriate relief, seeking the disclosure and release of agency records that have been improperly withheld from Hygia Health Services, Inc. ("Hygia" or "Plaintiff") by the United States Food & Drug Administration ("FDA" or "Defendant").

## Jurisdiction and Venue

2. This Court has jurisdiction over this action under both 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper in this district under 5 U.S.C. § 552(a)(4)(B).

3. Hygia is a privately-owned corporation with its headquarters and principal place of business in Birmingham, Alabama. Hygia performs reprocessing services for single-use medical devices, such as single-use blood pressure cuffs, on behalf of hospitals in fifteen (15) states including Alabama. Hygia contracts with hospitals to collect these types of medical devices at their facilities, reprocesses them pursuant to FDA guidelines and regulations, and returns them to the source hospital for reuse.

4. FDA is an agency of the Executive Branch of the United States Government and is a component of the United States Department of Health and Human Services ("HHS"). FDA is an agency within the meaning of 5 U.S.C. § 552(f).

5. FDA is not a criminal law enforcement authority within the meaning of 5 U.S.C. § 552(b)(7)(D).

**Factual Allegations**

6. By letter dated July 6, 2006, FDA issued to Hygia an Establishment Inspection Report ("EIR") for an inspection conducted by FDA at Hygia's reprocessing facility on March 13-17, 2006. A true and correct copy of the EIR as disclosed to Hygia by FDA is attached hereto as Exhibit 1.

7. FDA has concluded that its inspection of Hygia is closed and has determined not to take any further action on the matters considered in the EIR.

8. FDA's inspection of Hygia's reprocessing facility on March 13-17, 2006, was not a national security intelligence investigation within the meaning of 5 U.S.C. § 552(b)(7)(D).

9. On page 27 of the EIR, FDA disclosed that there are multiple supporting "Attachments" to the EIR. FDA described two of the attachments to the EIR as: 1) "Hygia Inspectional Report by Steven E. Turil, Biologist, CDRH/ODE"; and 2) "Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA." FDA did not provide the attachments to Hygia when it issued the EIR.

10. By letter dated July 11, 2006, Hygia requested from FDA, pursuant to FOIA, copies of the "Hygia Inspectional Report by Steven E. Turil, Biologist, CDRH/ODE" and the "Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA," which FDA had previously stated were supporting attachments to the EIR. A true and correct copy of Hygia's FOIA request is attached hereto as Exhibit 2.

11. By letter dated August 21, 2006, FDA provided its initial response to Hygia's FOIA request. In its initial response, FDA released in part and withheld in part the "Hygia Inspectional Report by Steven E. Turil, Biologist, CDRH/ODE." FDA did not cite to any FOIA exemption as justification for withholding portions of the "Hygia Inspectional Report by Steven E. Turil, Biologist, CDRH/ODE" nor did it provide any other justification or explanation of the withholding. A true and

correct copy of FDA's August 21, 2006 initial response is attached hereto as Exhibit 3.

12. By letter dated September 15, 2006, FDA provided its final response to Hygia's FOIA request. In its final response, FDA denied in full the remainder of Hygia's FOIA request, including Hygia's request for the "Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA." As grounds for its denial, FDA cited FOIA Exemptions 7(C) and 7(D), 5 U.S.C. § 552(b)(7)(C), (D), and FDA and HHS regulations implementing FOIA Exemptions 7(C) and 7(D).

13. Hygia received FDA's final response on September 20, 2006. A true and correct copy of FDA's September 15, 2006 final response is attached hereto as Exhibit 4.

14. FDA has not sent Hygia an invoice for charges incurred in responding to Hygia's FOIA request.

15. On October 18, 2006, Hygia filed an administrative appeal with HHS from the denial of records by FDA. A true and correct copy of Hygia's administrative appeal is attached hereto as Exhibit 5.

16. By letter dated October 19, 2006, HHS acknowledged receipt of Hygia's administrative appeal. HHS assigned Hygia's appeal the number PHS-2K7-A-010. A true and correct copy of HHS's acknowledgment of receipt is attached hereto as Exhibit 6.

17. More than twenty (20) working days have elapsed since HHS received Hygia's administrative appeal.

18. HHS has not notified Hygia of any determination with respect to Hygia's administrative appeal.

**Hygia is Entitled to Relief based on FDA's Improper Withholding of Agency Records**

19. FDA has wrongfully withheld portions of the "Hygia Inspectional Report by Steven E. Turil, Biologist, CDRH/ODE" and has wrongfully withheld in its entirety the "Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA."

20. FDA has failed to comply with the applicable time limits required under FOIA.

21. Hygia has exhausted the applicable administrative remedies.

**Requested Relief**

WHEREFORE, Plaintiff requests that this Court:

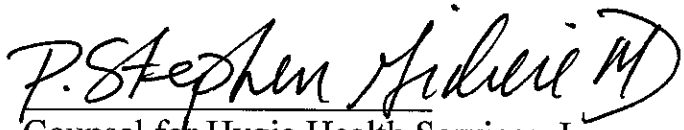
A. Issue an injunction ordering FDA to disclose the requested records to Hygia in their entirety;

B. Provide for the expeditious processing of this action;

C. Award Plaintiff its costs and reasonable attorney fees incurred in this action; and

D. Order such other relief as the Court may deem just and proper.

Respectfully submitted,



Counsel for Hygia Health Services, Inc.

**Counsel for Hygia Health Services, Inc.:**

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# EXHIBIT 1

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**
**New Orleans District**
**Southeast Region**
**297 Plus Park Boulevard**
**Nashville, TN 37217**

**Telephone: (615) 781-5380**
**Fax: (615) 781-5391**

July 6, 2006

Mr. Scott Comas, President
Hygia Health Services, Inc.
434 Industrial Lane
Birmingham, AL 35211

Dear Mr. Comas:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at the above address on March 13 – 17, 2006, by the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under Public Information, Title 21, *Code of Federal Regulations*, (CFR) Part 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This new procedure is applicable to the EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and Title 21, CFR Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to contact me, at (504) 219-8818 or write to U.S. Food and Drug Administration, 2424 Edenborn Avenue, Suite 410, Metairie, LA 70001.

Sincerely,

Rebecca A. Asente

Rebecca A. Asente
Acting Compliance Branch Director
New Orleans District

Enclosure

| | |
|---|---|
| 22.1-.12 | Design Control SOP, dated 3/8/06 |
| 23.1-.5 | Device Push-Through Protocol – Aircast |
| 24.1 | Design Inputs (DHR) for the Aircast Compression Sleeves |
| 25.1-.6 | Document Control SOP, dated 3/13/06 |
| 26.1-.3 | Microbial Testing for HLD Verification and Environmental Controls SOP |
| 27.1-.3 | Control of Non-Conforming Product SOP, dated 7/28/03 |
| 28.1 | Monthly Equipment Inspection schedule for October to December of 2005 |
| 29.1-.2 | Equipment Log |
| 30.1-.14 | Cleaning/Maintenance Procedure, dated 1/5/06, for conducting maintenance |
| 31.1-.2 | Complaint Log listing complaints since the last inspection |
| 32.1-.6 | Complaint #77, dated 10/26/05 |

**ATTACHMENTS**

FDA-482, Notice of Inspection
FDA-483, Inspectional Observations
Hygia Inspectional Report by Steven E. Turtil, Biologist, CDRH/ODE
Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA

Carolyn E. Barney

Carolyn E. Barney
Investigator SHV-RP
New Orleans District

# EXHIBIT 2

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

July 11, 2006

Re: FEI 3002784809

Dear Sir/Madam:

Please accept this request, in compliance with the Freedom of Information Act, for certain documents referenced in the Establishment Inspection Report (EIR) for Hygia Health Services, Inc of Birmingham, AL conducted March 13-17, 2006. The inspection was classified as "closed" in a letter from Rebecca A. Asente, Acting Compliance Branch Director, New Orleans District dated July 6, 2006.

Specifically, I would like copies of:

1.) Hygia Inspectional Report by Steve E Turtil, Biologist, CDRH/ODE
2.) Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA

Each of these documents is noted in the "Attachments" section on page 27 of the EIR.

Hygia is willing to pay the fees associated with this request.

Thank you and please contact me with any questions.

Sincerely,

Scott Comas
President, Hygia Health Services, Inc
205-314-3920

# EXHIBIT 3

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration
New Orleans District
Southeast Region
297 Plus Park Blvd.
Nashville, TN 37217-1003
Telephone: 615-781-5385
Fax: 615-781-5391

August 21, 2006

Mr. Scott Comas, President
Hygia Health Services
434 Industria Lane
Birmingham, Alabama 35211

Re: FOI# 2006-11408

Dear Mr. Comas:

This is in regard to your Freedom of Information request for copies of the attachments in your July 11, 2006, request. Enclosed you will find the following: Hygia Inspectional Report by Steve E. Turtil dated March 23, 2006 (5 pages). You will hear from another FDA office regarding the remainder of your request.

As you will note, the enclosed record contains certain personal information which is disclosable only to your firm. Copies of these records will be disclosed to other requesters only after thorough review and deletion of those portions which are not disclosable to the general public.

The following charges may be included in a monthly invoice:

Search $ 10.00 Review $ 20.00 Duplication $ 0.50 **Total $ 30.50**

The above total may not reflect final charges for this request. Please **DO NOT** send payment unless you receive an invoice.

Sincerely,

Patricia K. Schafer
Compliance Branch Director
New Orleans District

Enclosure

Department of Health & Human Services

Public Health Service
Food & Drug Administration

# Memorandum

**DATE:** March 23, 2006

**FROM:** Steven Turtil, Biologist, Infection Control Devices Branch (INCB)
**THROUGH:** Sheila Murphey, Branch Chief, INCB, DAGID
**TO:** Carolyn Barney, Lead Investigator, New Orleans District

**SUBJECT:** Hygia Health Services Investigation: Reprocessed Pulse Oximeter Probes, Blood Pressure Cuffs, and Limb Compression Sleeves

The following is a summary of the events and findings resulting from my review activities during the week of March 13 to March 17, 2006, at Hygia Health Services, of Birmingham, Alabama.

## GENERAL

A previous inspection was conducted 10 months ago, in May, 2005, as a [redacted]

[redacted]

Lead Investigator, Carolyn Barney, of the Shreveport, Louisiana, Residence Post (ORA) decided to notify the firm of the inspection 2 days in advance, in order to insure that all company officers would be present. [redacted]

[redacted]

## HISTORY

This company is on record as having submitted thirteen 510(k) applications, 11 of which are active, 1 of which was deleted, and 1 of which was withdrawn. All devices are "Spaulding" non-critical, intact skin contacting devices, which fall into 3 categories: Pulse Oximeters, Limb Compression Sleeves, and Blood Pressure Cuffs. All devices undergo cleaning procedures. Pulse Oximeters and Limb Compression Sleeves are subjected to "Pasteurization" while the Blood Pressure Cuffs are treated with a Hypochlorite solution. Both are considered High Level Disinfection by Hygia.

Of the 11 active 510(k) applications, only the Pulse Oximeters were subject to Supplemental Validation Data requirements as reprocessed single use devices (SUDs) per the Medical Device User Fee and Modernization Act of 2002. These are identified as K012715 for which I was the INCB consult reviewer (April and July of 2004), as well as K041867. It is unclear whether or not file K041867 included, and was reviewed for, Supplemental Validation Data.

Since the May, 2005, inspection, [redacted] The inspection was conducted by Carolyn Barney and myself, [redacted]. Representatives included Mr. Scott Comas, President; Ms. Tracy Coma, COO; Mr. Michael Burnell, Quality Assurance Director, and Dr. James Farmer III, Consultant. Hygia Health Services was cooperative in regard to all information requests.

The firm reprocesses about 400 Blood Pressure Cuffs, 800 Pulse Oximeters, and 800 Limb Compression Sleeves per day.

## EVALUATION

This inspection was conducted in accordance with the QSIT manual (Quality System Inspection Techniques) and in accordance with the CFR Part 820. In addition, processes, product, and final labeling were evaluated in accordance with the 1996, ODE publication, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance."

### FDA Guidance and Context

INCB has evaluated about eight 510(k) applications for reprocessed Pulse Oximeters, all during the middle of 2004. It was established by consensus within INCB at that time that these devices should meet the minimum recommendations stated in the "Labeling Reusable Medical Devices..." guidance mentioned above, for devices contacting intact skin. This specified that the devices be "thoroughly cleaned" and meet the endpoint of "visually clean" or "no visual contamination."

Hygia appears to have a rigorous cleaning process for all devices. Cleaning involves the use of Oxyclean detergent, hydrogen peroxide, and isopropyl alcohol. Devices undergo from 1 to 3 visual inspections and require the end product to be visually clean. This appears to be adequate.

### Cleaning and Pasteurization

Hygia appears to have procedures in place that adequately provide "thorough cleaning" and meet the "no visual contamination" endpoint that have been accepted by the FDA for other reprocessors of non-critical SUDs (with the exception of those labeled "Sterile"). In addition, Hygia appears to have gone above and beyond the minimal cleaning procedures for non-critical devices by implementing a what they refer to as a "Pasteurization" process.

Prior to this inspection, concerns about the validation and adequacy of the "Pasteurization" process were brought to the attention of the Office of Compliance (OC) as well as to the attention of the Lead Investigator, Carolyn Barney.

FDA considers "Pasteurization" to be a "high level disinfection" (HLD) method. Upon our investigation it appeared that there were no adequate validation studies on record. Information regarding bioburden before and after processing was available which indicated attainment of a 1 log reduction in vegetative cells, at best. Methods appeared inadequate as no product inoculation was performed, no positive controls were included in testing, and bioburden sampling involved "swabbing" the product instead of whole product exhaustive extraction.

However, all of Hygia's products are labeled as "Non-sterile." While Hygia has an HDL method in place that has not been adequately validated, there is no labeling claim made regarding high level disinfection. [redacted]

1. It appeared that OC was concerned that an unvalidated HLD process may be in place.
2. It was unclear whether or not all processes that are in place are required to be validated, regardless of any lack of claims.

I called Candace McManus of OC for Agency concurrence that the HLD processing did not have to be validated as long as no labeling claims were associated with it. Similarly, Carolyn Barney called Jan Welch of OC and received assurance that just because a process is in place, doesn't mean it has to be validated (again provided that no labeling claims were associated with it).

Following these OC contacts, Tracy Comas, Michael Burnell, and Jim Farmer were advised that if they use a general disinfection procedure such as the "Pasteurization" methods they have implemented, and if there is no claim in their labeling of high level disinfection or any other type of disinfection, the complete validation of that process is not necessary. They were further advised that if they intend to use it to support high level disinfection claims in the future or for other product lines, FDA would expect to see complete process validation. It was stated that the absence of any 483 citations on their "Pasteurization" should not be construed as an approval or endorsement of their "Pasteurization" methods, and that our current inspection activities do not constitute an evaluation and review of their HLD process.

(As an example, it was explained that if a company "sterilizes" product, but the process validation showed failures (e.g., growth in ½ cycle samples), then the overall processes would be acceptable provided the product was not labeled "sterile".)

**There is agreement among FDA representatives from across all three Offices, ODE, OC, and ORA, that Hygia's high level disinfection process does NOT have to undergo process validation, as no labeling claim is associated with it.**

It was concluded that adequate controls exist for the cleaning and disinfection processes.

**Water Quality**

Prior to this inspection, it was brought to the attention of OC that the reverse osmosis (RO) water system had not been fully validated. An RO water system would be above and beyond what is needed to meet the cleaning endpoints, and at the same time might actually create problems that could compromise product quality. It was established that no RO water system was present. A "Hague WaterMax" (ionic) water filtration system was in place, and appeared to be adequately maintained with a monthly salt check and an annual servicing. This appeared to be adequate.

**Biocompatibility**

The only biocompatibility issue that existed was related to the Blood Pressure Cuffs that were treated with a 15 minute soak in a 1:100 dilution of hypochlorite (600 ppm). (All other products underwent the "Pasteurization" process in water. (The cleaning steps involve the use of Oxyclean detergent (a derivative of hydrogen peroxide), hydrogen peroxide, and isopropyl alcohol, all of which are known to have limited and low risk residues, and all of which were followed by rinse cycles.

Biocompatibility data consisted of Skin Irritation and Skin Sensitization testing. A total of 12 devices were tested, and subjects were evaluated at 24 and 48 hours. All readings scored as "0" with only a few "1A" indicating very mild reactions. Data was acceptable.

**Design Control**

Questions arose regarding what constituted "Design Control" for a reprocessed SUD: it was unclear whether the proper subject was the device, or the processes, or what combination of the two. Jan Welch provided the guidance that we could accept information that was presented in the 510(k) application as adequately addressing the design control requirements. It was resolved between Carolyn Barney and Jan Welch that this did not remain a concern.

**Functionality Testing**
Proper validation of cleaning, disinfection, and/or sterilization process typically involves measures of both microorganism reduction, as well as functionality testing. Since we have established that HLD validation for these devices is unnecessary, we decided to accept that 100% device functionality verification was adequate.

**Software Validation**
Software was designed and implemented by a local software company and designated the "HART" system (Hygia Automated Reporting and Tracking). Validation documentation appeared to be in place. "Black Box" testing for "off-the-shelf" software was part of this process.

**Procedures and Gap Analysis**
Significant progress has been made since the previous inspection.

Jim Farmer (previously of CDC) is the firms Infection Control Coordinator.

William Jackson was hired as an additional GMP Consultant and conducted a "Gap Analysis" of the in-house processes and documentation. It appears that many of the previous deficiencies have been adequately addressed: new procedures have been drafted and others have been finalized. Not all deficiencies have been addressed, as some procedures remain to be provided in greater detail. However, what remains may be consistent with the amount of time allowed since the previous inspection.

In addition, Michael Burnell began working for Hygia as of the beginning of March, 2006, as Quality Assurance Director.

**510(k) Records and Labeling**
All 510(k) products matched the Agency's records. The particular devices that were the subject of the SVS applications – that is, the Adult, Pediatric, Infant, and Neonatal models – were properly accounted for. A review of packaging and labeling established that all Class II devices were appropriately labeled with regard to:

- Being labeled Non-sterile,
- Being labeled Single Use,
- Being labeled Reprocessed,
- Identification of the Reprocessor, Hygia,
- Identification of the original equipment manufacturer. (The exception is a generic label for all blood pressure cuffs bundled within K053575 – multiple manufacturers. It is unclear whether this will be a requirement at all, or if it will be a requirement effective August, 2006),
- The Device Common Name, and
- Content (number per package).

**MDRs and Complaints**
No MDRs have been filed. Procedures appear to be in place for complaints, but clarifications are still needed. For example, one complaint regarding 5 leaking blood pressure cuffs was recorded as a single complaint, when it should have been recorded as 5 separate complaints.

## RECOMMENDATION

[redacted] have either been adequately addressed, or [redacted] method, while not validated, does go above and beyond the methods and endpoints established by INCB as relevant for non-critical devices. Water quality issues raised in advance of this inspection are not relevant for these device types. Neither the "Pasteurization" process nor water quality systems that are in place, appear to adversely affect product quality.

Furthermore, as expressed by Carolyn Barney, it appears that significant progress has been made regarding improvement of quality systems and procedures since the previous inspection.

The addition of a Quality Assurance Director and an outside consultant [redacted] While improvements are still warranted, the progress that has been made since the last inspection is consistent considering the elapsed time.

# EXHIBIT 4

**DEPARTMENT OF HEALTH & HUMAN SERVICES** **Public Health Service**

**Food and Drug Administration**
**Rockville, MD 20857**

Date: SEP 15 2006

RECEIVED
Date: 9-20-06

Request Number: 06-11408

Scott Comas
Hygia Health Services
434 Industria Lane
Birmingham, AL 35211

Subject of Request: Attachment to an Establishment Inspection Report

Dear Sir/Madam:

The Food and Drug Administration (FDA) has completed processing your request for records under the Freedom of Information Act (FOIA). I apologize for any delay in responding to you. The paragraphs checked below apply to your request:

[X] We have already released certain materials to you and are denying the remainder of your request.

[ ] We are denying your entire request.

[X] The following exemption(s) of FOIA, 5 U.S.C. 552, indicated by an "X" is/are the authority for denying you access to the non-disclosable material. We have enclosed copies of FOIA and regulations for your information.

[ ] (b)(1) National security information concerning the national defense or foreign policy
[ ] (b)(2) Internal rules and practices
[ ] (b)(3) Prohibited from disclosure by other laws
[ ] (b)(4) Trade secret and confidential commercial information
[ ] (b)(5) Certain interagency and intra-agency communications
[ ] (b)(6) Information about individuals in personnel, medical and similar files when disclosure would constitute a clearly unwarranted invasion of privacy
[X] (b)(7) Records or information compiled for law enforcement purposes when disclosure
  [ ] (A) could reasonably be expected to interfere with enforcement proceedings
  [ ] (B) would deprive a person of a right to a fair trial or an impartial adjudication
  [X] (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy
  [X] (D) could reasonably be expected to disclose the identity of a confidential source

[ ] (E) would disclose techniques, procedures or guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law

[ ] (F) could reasonably be expected to endanger the life or physical safety of an individual

[X] The following section(s) of the implementing regulations of the Department of Health and Human Services (DHHS) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 45.

| | |
|---|---|
| [ ] 5.63 | [ ] 5.68(a) |
| [ ] 5.64 | [ ] 5.68(b) |
| [ ] 5.65 | [X] 5.68(c) |
| [ ] 5.66 | [X] 5.68(d) |
| [ ] 5.67 | [ ] 5.68(e) |
| | [ ] 5.68(f) |
| | [ ] Other: |

[X] The following section(s) of the implementing regulations of FDA and reason(s) applicable to this denial is/are indicated by an "X". The regulations are contained in the Code of Federal Regulations (CFR), Title 21.

[X] 20.64(a)(3) and (a)(4) Record(s) compiled for law enforcement purposes, the disclosure of which could reasonably be expected to constitute an unwarranted invasion of the personal privacy of the individual(s) identified in the document(s), and disclose the identify of a confidential source, such as a consumer complainant, and confidential information furnished by that source, in general.

[ ] Other laws, in addition to FOIA, may prohibit disclosure of the information you requested. The following law(s) applicable to this denial is/are indicated by an "X".

[ ] 18 U.S.C. 1905 [Federal Trade Secrets Act]
[ ] 21 U.S.C. 331(j) [Federal Food, Drug, and Cosmetic Act]
[ ] 21 U.S.C. 360j(c) [Federal Food, Drug, and Cosmetic Act]
[ ] 5 U.S.C. 107(a)(2) Appendix 4 [Ethics in Government Act]

[X] The estimated volume of the records we are denying is: 6 pages.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. You should file any such appeal within 30 days and address it to the Deputy Assistant Secretary for Public Affairs (Media), U.S. Department of Health and Human Services, Room 17A-46, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely yours,

Julie Zawisza
Assistant Commissioner for
Public Affairs

Enclosures, as indicated

# EXHIBIT 5

BALCH & BINGHAM LLP

Alabama • Georgia • Mississippi • Washington, DC

P. Stephen Gidiere III
(205) 226-8735

Attorneys and Counselors
1901 Sixth Avenue North, Suite 2600
P.O. Box 306 (35201-0306)
Birmingham, Alabama 35203-2628
(205) 251-8100
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(205) 488-5694 (direct fax)
sgidiere@balch.com

October 18, 2006

VIA FEDERAL EXPRESS and FACSIMILE (301-443-0925)

Deputy Assistant Secretary for Public Affairs (Media)
U.S. Department of Health and Human Services
Room 17A-46
5600 Fishers Lane
Rockville, Maryland 20857

RE: Freedom of Information Act ("FOIA") Appeal, Request Number 06-11408

Dear Sir/Madam:

On behalf of Hygia Health Services ("Hygia"), I am filing this FOIA appeal from the denial of records by the Food and Drug Administration ("FDA"). Hygia's FOIA request was submitted to FDA on July 11, 2006 (attached at Tab 1). The request asked for two attachments that were specifically identified on the last page of an Establishment Inspection Report ("EIR") issued by FDA dated July 6, 2006 (attached at Tab 2). The attachments requested by Hygia were described by FDA in the EIR as:

1) Hygia Inspectional Report by Steve E. Turtil, Biologist, CDRH/ODE

2) Alliance Medical Corporation Trip Report, dated 2/28/05 to FDA

FDA responded to the request in two installments. By letter dated August 21, 2006, FDA released the Hygia Inspectional Report in part, redacting certain information without providing citation to any FOIA exemption or other explanation (attached at Tab 3). By letter dated September 15, 2006, FDA provided its final response and denied access to the Alliance Medical Corporation Trip Report in its entirety (attached at Tab 4). As grounds, FDA cited FOIA Exemptions 7(C) and 7(D). Hygia received FDA's final response on September 20, 2006.

As discussed below, FDA should release both documents in their entirety.

**1. FDA Has Failed to Provide Any Grounds for Withholding the Hygia Inspectional Report in Part**

When an agency decides to withhold a record from a FOIA requester in whole or in part, the statute requires the agency to "notify the person making such request of such determination and the reasons therefor." 5 U.S.C. § 552(6)(A)(i) (emphasis added). FDA has utterly failed in

this regard with respect to the Hygia Inspectional Report. FDA's August 21, 2006 letter releasing in part and withholding in part the Hygia Inspectional Report gives no explanation or basis for the redactions. Because FDA does not claim that the redacted material is subject to a FOIA exemption, the report must be released in its entirety. *See Department of the Air Force v. Rose*, 425 U.S. 352, 361 (1976); *National Wildlife Federation v. United States Forest Service*, 861 F.2d 1114, 1116 (9th Cir. 1988) ("Unless documents fall within one of the nine specific exemptions to the disclosure requirement of the FOIA, they are presumed to be available for public inspection.").

**2. Exemption 7(C) Does Not Apply to the Alliance Medical Corporation Trip Report**

FOIA Exemption 7(C) applies to "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information . . . (C) could reasonably by expected to constitute an unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(7)(C). Applying Exemption 7(C) requires the agency to identify and balance the personal privacy and public interests at stake with regard to a particular record. *See Department of Justice v. Reporters Committee for Freedom of the Press*, 489 U.S. 749, 762 (1989).

FDA's denial letter does not evidence such a balancing by the agency with respect to the Alliance Medical Corporation Trip Report. If such a balancing were undertaken in this case, it would weigh heavily in favor of disclosure. Disclosure of the FDA's EIR *in full* (which includes its supporting attachments) would further the public's right "to be informed about what their government is up to" and would "shed[] light on an agency's performance of its statutory duties"—*i.e.*, how the FDA conducts its investigations and what information it uses to support its regulatory decisions. *Id.* at 773 (internal quotations omitted). These are the core functions of FOIA. *Id.* As to the privacy side of the equation, it is well-established that businesses and corporations do *not* have privacy interests that are protected under FOIA, and that individuals acting in a commercial capacity have a "diminished expectation of privacy." *See* U.S. Department of Justice, *Freedom of Information Act Guide & Privacy Act Overview*, at 439 (May 2004) ("DOJ FOIA Guide") (citing *Oregon Natural Desert Association v. Department of the Interior*, 24 F. Supp. 2d 1088 (D. Or. 1998)). As one court explained in an Exemption 7(C) case: "The privacy exemption does not apply to information regarding professional or business activities. This information must be disclosed even if a professional reputation may be tarnished." *Cohen v. Environmental Protection Agency*, 575 F. Supp. 425, 429 (D.D.C. 1983) (internal citation omitted). Thus, because FDA's EIR makes clear that the Alliance Medical Corporation Trip Report was submitted to FDA by a business and competitor of Hygia (*i.e.*, Alliance Medical Corporation), FDA's reliance on Exemption 7(C) is in error.

**3. Exemption 7(D) Does Not Apply to the Alliance Medical Corporation Trip Report**

FOIA Exemption 7(D) permits an agency to withhold "records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information . . . (D) could reasonably be expected to disclose the identity of a confidential source, including . . . any private institution which furnished information on a confidential basis." 5 U.S.C. § 552(b)(7)(D).

Exemption 7(D) does not apply here because disclosure of the Alliance Medical Corporation Trip Report could not reasonably be expected to reveal the identity of a "confidential source." Importantly, "the identity" of the alleged "confidential source" of the report is already clearly identified in FDA's EIR as Alliance Medical Corporation. Thus, it is hard to imagine how FDA could credibly argue that the source of the Alliance Medical Corporation Trip Report was a "confidential source" when FDA has already disclosed that it was Alliance Medical Corporation that provided the Trip Report "to FDA." *See* Tab 2 at 27. Exemption 7(D) only protects a source's identity when the source has provided the information under an express promise of confidentiality or "under circumstances from which such an assurance could be reasonably inferred." DOJ FOIA Guide at 606. In this case, FDA's decision to disclose the identity of the source of the Trip Report as Alliance Medical Corporation belies any assertion by FDA now that there was an express or implied assurance of confidentiality.

Moreover, even if Exemption 7(D) did apply, because FDA has already disclosed the identity of the source of the report when it released the EIR, it cannot withhold such identity information now. *See* 21 C.F.R. § 20.81 ("Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public . . . ."). Thus, FDA's withholding of the identity of the source of the Alliance Medical Corporation Trip Report is a violation of FDA's own regulations, in addition to a violation of FOIA.

In addition to identity information, Exemption 7(D) can apply to the actual "information furnished by a confidential source" in certain situations. 5 U.S.C. § 552(b)(7)(D). This aspect of Exemption 7(D) does not justify the withholding of the contents of the Alliance Medical Corporation Trip Report. As a threshold matter, the contents of the report were not "furnished by a *confidential* source," as discussed above, because FDA has already disclosed the source of the report. Moreover, this aspect of Exemption 7(D) only applies "in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation." *Id.* Neither is the case here. FDA is not a "criminal law enforcement authority." And even if FDA could be considered a "criminal law enforcement authority" because of its mixed-function status, its investigation in this case was civil in nature, not criminal, as evidenced by the EIR. Finally, it is obvious that FDA was not "conducting a lawful national security intelligence investigation" in its inspection of Hygia. Exemption 7(D) simply does not apply to any aspect of the Alliance Medical Corporation Trip Report.

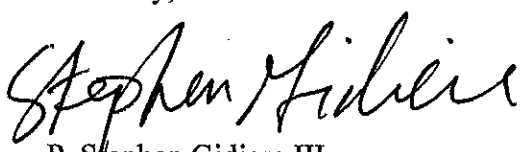
**4. At a Minimum, FDA Must Release "Reasonably Segregable" Non-Exempt Portions of the Alliance Medical Corporation Trip Report**

FOIA requires FDA to release any reasonably segregable portion of a record after deletion of portions which are exempt. 5 U.S.C. § 552(b). This obligation to release non-exempt portions of a record extends to all FOIA's exemptions, including Exemption 7. *See* DOJ FOIA Guide at 599 ("In any event, of course, agencies should be sure to redact their law enforcement records so that only identifying information is withheld under Exemption 7(C).") (emphasis added).

Courts require that agencies "must provide a reasonably detailed justification rather than conclusory statements to support its claim that the non-exempt material in a document is not reasonably segregable." *Voinche v. Federal Bureau of Investigation*, 412 F. Supp. 2d 60, 70 (D.D.C. 2006). Even if FDA continues to maintain that the name, address, phone number, or other information that might identify the source of the Alliance Medical Corporation Trip Report is exempt (either as personal privacy information or confidential source information), the FDA has not, and cannot, provide a detailed justification for withholding the remainder of the report. In fact, FDA's practice in other cases involving privacy concerns is to redact names and addresses and disclose the remainder of the document. *See, e.g., Judicial Watch, Inc. v. Food & Drug Administration*, 449 F.3d 141, 152 (D.C. Cir. 2006). FDA's failure to follow this practice with respect to the Alliance Medical Corporation Trip Report is arbitrary and capricious and would be indefensible in court. At a minimum, FDA must release the Alliance Medical Corporation Trip Report after redaction of specifically exempt items of information.

I look forward to your action on this appeal within twenty (20) working days.

Sincerely,



P. Stephen Gidiere III

PSG: jb

cc: Mr. Scott Comas, Hygia Health Services

# EXHIBIT 6

DEPARTMENT OF HEAL & HUMAN SERVICES
Program Support Center

Public Health Service
Freedom of Information Office
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Rockville, MD 20857
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October 19, 2006

P STEPHEN GIDIERE III
BALCH & BINGHAM LLP
1901 SIXTH AVE NORTH STE 2600
BIRMINGHAM AL 35203-2628

Dear P STEPHEN GIDIERE III:

This is to acknowledge receipt of your administrative appeal dated 10/18/2006.

Any questions regarding the status of your appeal should be directed to the Public Health Services (PHS) Freedom of Information (FOI) office.

Your appeal has been assigned the following number PHS-2K7-A-010.

Please reference this number on your correspondence.

Sincerely,

PHS Freedom of Information Office